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ABSTRACT

Objective. The aim of this study was to evaluate whether the scrupulous hygiene rules and the restriction of contacts during the lockdown owing to the COVID-19 pandemic affected the rate and severity of surgical site infections (SSI) after vascular exposure in the groin at two Italian University Hospitals.

Methods. Starting from March 2020, strict hygiene measures for protection of HCW and patients from COVID-9 infection were implemented, and partly lifted in July 2020. The main exposure for analysis purposes was the period in which patients were operated. Accordingly, study subjects were divided into two groups for subsequent comparisons (pre-COVID-19 era: March-June 2018-2019 vs COVID-19 era: March-June 2020). The primary endpoint was the occurrence of superficial and/or deep SSI within 30 days after surgery. The Centers for Disease Control and Prevention definitions were used to classify superficial and deep SSI.

Results. A total of 194 consecutive patients who underwent vascular exposure in the groin were retrospectively analyzed. Of those, 60 underwent surgery from April 1, 2018 to June 30 of the same year; 83 from April 1, 2019 to June 30 of the same year; and 51 from April 1, 2020 to June 30 of the same year. The mean age of the study cohort was 75 years and 140 (72%) were males. Patients who were operated in the COVID-19 era were less likely to develop SSI (10% vs 28%; p=.008), including both deep SSI (4% vs 13%; p=.04) and superficial SSI (6% vs 15%; p=.05). After multivariate adjustments, being operated in the COVID-19 era was found to be a negative predictor for development of an SSI (OR=0.31; 95%CI=0.09-0.76; p<.001) or deep SSI (OR=0.21; 95%CI=0.03-0.98; p<.001). Operative time was also found as independent predictor for development of deep SSI (OR=1.21; 95%CI=1.21-1.52; p=.02). Using binary logistic regression there were no independent predictors of superficial SSI that could be identified.

Conclusions. Vascular exposure in the groin carries a non-negligible risk of SSI. In this study, we provided important insights that simple and easily viable precautions (such as the universal use of surgical masks both for patients and healthcare professionals during wound care, the widespread diffusion of hand sanitizers, and the reduction of the number of visitors in the surgical wards) could be promising and safe tools for SSI risk reduction.

Keywords. Vascular surgery; Surgical site infection; Perioperative outcomes; Femoral artery; Groin; COVID-19.

INTRODUCTION

Surgical site infections (SSI) are the most commonly in-hospital acquired infections[1], and SSI after vascular exposure in the groin are still commonplace following arterial interventions[2]. Deep SSI in particular may account for a significant proportion of these infections, carrying a risk of re-intervention, prolonged hospitalization, increased costs, major lower limb amputation, or even death. As such, recent guidelines on the management of vascular graft infections highlight the importance of identifying and understanding risk factors in relation to SSI[3].

There are many ways to reduce the rate of SSIs, and optimization of potentially modifiable patient-level (e.g., smoking cessation, optimal glycemic control, screening for multi-drug resistant bacteria) and procedure-level (e.g. skin disinfection, antibiotic prophylaxis, careful surgical wound dressing) risk factors is the first step to pursue in the prevention of SSI. Indeed, the World Health Organization (WHO) has introduced the “global guidelines for the prevention of SSI” where preoperative and intraoperative measures are highlighted that may reduce the incidence and severity of SSI[4]. Concerning the postoperative prevention of SSI, it is necessary to use a bundle of strategies, with meticulous hand hygiene and asepsis during wound care being the cornerstone of care[5-8].

The SARS-CoV-2 pandemic has led to adding other recommendations to those guidelines. In particular, the WHO recommended increased precautions be taken by healthcare workers (HCW) to protect themselves and patients from virus infection[9, 10]. These measures included the constant use of a face mask (e.g., surgical masks, FFP-2, FFP-3, KN95), mandatory use of gloves, frequent hand-rubbing with alcoholic solution, and limited movement of staff and patients including restricted access for relatives or caregivers (*Figure 1*).

The aim of this study was to evaluate whether the scrupulous hygiene rules and the restriction of contacts during the lockdown owing to the COVID-19 pandemic affected the rate and severity of SSI after vascular exposure in the groin at two Italian University Hospitals.

METHODS

Study design. Starting from March 2020, strict hygiene measures for protection of HCW and patients from COVID-9 infection were implemented, and partly lifted in July 2020. The main exposure for analysis purposes was the period in which patients were operated. Accordingly, study subjects were divided into two groups for subsequent comparisons (pre-COVID-19 era: March-June 2018-2019 vs COVID-19 era: March-June 2020). All patients were routinely followed-up in the outpatient clinic for 30 days after surgery. Eligible patients included those of 18 years and older undergoing elective or emergency surgical procedures that required vascular exposure in the groin including Fogarty embolectomy, femoral endarterectomy, and femoropopliteal bypass. Local departmental structures approved the study which did not alter routine standards of care delivered to patients. Retrospectively collected data included baseline demographics, cardiovascular risk factors and medical comorbidities, chronic medications, and operative details. Surgical risk was defined according to the Society for Vascular Surgery and American Society of Anesthesiology risk scores.

Surgical practice. All patients were admitted to the surgical ward only if they had a negative COVID-19 swab.in the last 48 hours. Most patients received antibiotic prophylaxis with Cefazoline 2g according to the surgical departments' guidelines. The antibiotic was re-dosed if the operation lasted longer than 4 hours. Prolonged antibiotic therapy lasting more than 24 hours after the surgical operation were prescribed on a case-by-case basis as clinically needed. The surgical site was prepared with a careful skin disinfection using iodine povidone or, alternatively, chlorhexidine alcohol if allergies were present. All groin incisions were done in longitudinal fashion, as this represents the routine approach to vascular exposure in the groin at the study centers.

Statistical analysis. The primary endpoint was the occurrence of superficial and/or deep SSI within 30 days after surgery. The Centers for Disease Control and Prevention definitions were used to classify superficial and deep SSI. Secondary endpoints included mortality and major lower limb amputation within 30 days from index operation. All data were evaluated for normality with quantile-

quantile plots. Continuous variables are expressed with either mean or median values, with corresponding standard deviation (SD) or interquartile range (IQR). Categorical variables are presented as a percentage. Univariable analyses were carried out with either Student's T test for continuous variables, and chi-square test or Fisher's exact test for categorical variables. Binary logistic regression was used for the multivariate analysis to calculate odds ratios with 95% confidence intervals (CIs). Covariates for these models were selected based on univariate screen of all available potential confounders and stepwise backward regression to fit the model. Data were analysed using IBM SPSS Statistics 24 (IBM, Armonk, NY). A $P < 0.05$ was considered statistically significant.

RESULTS

Baseline characteristics. A total of 194 consecutive patients who underwent vascular exposure in the groin were retrospectively analyzed. Of those, 60 underwent surgery from April 1, 2018 to June 30 of the same year; 83 from April 1, 2019 to June 30 of the same year; and 51 from April 1, 2020 to June 30 of the same year. The mean age of the study cohort was 75 years and 140 (72%) were males (*Table I*). At baseline, patients operated in the COVID-19 era had lower hemoglobin values (p=.04) and were more likely to be anemic before the operation (p=.04). Also, they were less likely to undergo urgent operations (p=.02) but underwent more complex procedures that required more often the association of distal endovascular interventions (p=.004) and had longer operative times (p<.001). When comparing patients who were operated in the two years that comprised the pre-COVID-19-era, no significant differences were found in terms of baseline demographics, risk factors, or procedural details.

Clinical outcomes. Patients who were operated in the COVID-19 era were less likely to develop SSI (10% vs 28%; p=.008), including both deep SSI (4% vs 13%; p=.04) and superficial SSI (6% vs 15%; p=.05) (*Figure 2*). No significant differences were found in the rate of SSI in the years 2018 vs. 2019 (pre-COVID-19 era). Also, no significant differences were found in the rates of lower limb amputation or early mortality when comparing the pre-COVID-19 era (years 2018-2019) vs the COVID-19 era (year 2020).

Predictors of SSI. After multivariate adjustments, being operated in the COVID-19 era was found to be a negative predictor for development of an SSI (OR=0.31; 95%CI=0.09-0.76; p<.001) (*Table IIA*) or deep SSI (OR=0.21; 95%CI=0.03-0.98; p<.001) (*Table IIB*). Operative time was also found as independent predictor for development of deep SSI (OR=1.21; 95%CI=1.21-1.52; p=.02). Using binary logistic regression there were no independent predictors of superficial SSI that could be identified (*Table IIC*).

DISCUSSION

Reducing the occurrence of SSIs is the main focus of numerous quality improvement initiatives as they represent a common and costly cause of potentially preventable patient morbidity[11]. In vascular surgery, exposure of the femoral vessels in the groin remains burdened with a not-negligible rate of SSI and continues to attract notable research efforts in the contemporary era[12]. Indeed, SSI are associated with an increased risk of postoperative morbidity, prolonged hospitalization, postponement of rehabilitation, increased healthcare costs, and in some cases possibly poorer long-term outcomes due to a worsening of the overall clinical picture. However, in-depth analyses of this particular issue in vascular surgery patients during the COVID-19 pandemic has not been extensively investigated[13].

While some risk factors for SSI may be not modifiable, there exist some modifiable phenomenona that could be targeted with focused interventions to reduce the burden of SSI in the groin. The main findings of our study, which analysed 194 consecutive patients who underwent vascular exposure in the groin, were that those who were operated in the COVID-19 era (when more strict measures for the prevention of infectious disease transmission were taken) were less likely to develop SSI, both deep and superficial. To our knowledge this is one the largest available case-series of vascular surgical patients specifically evaluated for the incidence and severity of SSI during the lockdown for the SARS-CoV-2 pandemic but may serve to identify some important factors that can contribute to improve peri-operative care to vascular patients. Although some differences were noted in the technical details of the procedures that were performed during the COVID-19 era (such as the increase in operative time that was likely related to an increase in the complexity of procedures with more frequent hybrid operations and associated distal endovascular procedures, or the more frequent use of autologous vein-based patch for femoral reconstruction), it is unlikely they might have significantly contributed to the observed reduction in SSI rates.

Recently, the Surgical Care Improvement Project was created with the aim to reduce postoperative SSI by focusing on a series of pre-operative precautions such as prophylactic antibiotic administration, skin-hair clipping, and normothermia. However, despite evidence supporting the importance of these processes, high compliance is only weakly linked to improved outcomes. Several adjuncts aimed at reducing SSI have been evaluated in vascular groin wounds, including prophylactic closed incision negative pressure wound therapy (ciNPWT), local antibiotics, wound drains, platelet rich plasma, skin closure methods, fibrin glue, and silver alginate dressings[14, 15]. Although the evidence for ciNPWT's efficacy in reducing SSI in vascular groin wounds is encouraging[16, 17], data regarding the cost-effectiveness of their routine use are still lacking. In a recent systematic review on the effectiveness of wound adjuncts for prevention of SSI after vascular exposure in the groin[18], the use of ciNPWT was found to be as an effective intervention for preventing both superficial and deep SSI; available evidence suggested that local antibiotics do not reduce overall SSI rates, but may reduce superficial SSIs, and that subcuticular sutures, as opposed to other methods of closure, may also reduce the occurrence of SSI. However, all these interventions might entail significant additional costs, be difficult to implement in a homogeneous and capillary fashion or be possibly linked to harmful side effects for patients.

In contrast, in our study we were able to identify some preventive measures that, if adopted, could reduce the occurrence of SSI in the groin with an almost nihil risk of related adverse events to patients, without involving a dramatic increase in healthcare costs, and that could be broadly and easily implemented. Notably, as the only salient changes in surgical practice during the COVID-19 era were related to more strict hygiene measures (such as the universal use of surgical masks both for patients and healthcare professionals during wound care, the widespread diffusion of hand sanitizers, and the reduction of the number of visitors in the surgical wards), it would be reasonable to infer that such measures were implicated in the reduction of SSI rate in the groin[19].

Therefore, the above-mentioned initiatives can logically represent cost-effective preventive measures that would be worth incorporating into routine clinical practice even outside of the pandemic period. Future studies with larger samples will be needed to confirm these results and further improve the care of surgical wounds. However, owing to the intrinsic safety and reasonable cost-effectiveness of the hygienic measures that were identified in this study as potential factors underlying a significant decrease in SSI rates after vascular exposure in the groin, it would be reasonable to pay them further attention during clinical care in surgical wards. As for other types of vascular infections, the establishment of close multidisciplinary collaboration and definition of clear organizational models for integrated pathways of care might represent the most adequate steps to achieve further reduction in the rate of SSI[20, 21].

Study limitations. Findings from this study must be interpreted within the context of its limitations, including the retrospective design and relatively small sample size. However, data capture was highly accurate with missing values below 1% for all variables of interest and complete 30-day clinical assessment for all included patients. We tried to account for known confounders using multivariate adjustments, but the relatively small number of SSI and the short period of observation might underestimate the role of residual unknown confounders. In fact, while there have been a number of subsequent lockdown periods, the protocols during such periods have been less consistent as compared with the first pandemic wave (e.g. limited access to caregivers instead of totally restricted access) and more difficult to track. Although the COVID-lockdown period was characterized by a reduction of outpatient activities, the number of inpatient procedures remained quite stable (especially those for peripheral artery disease)[10]. Furthermore, the number of trainees as well as nursing-to-patient ratio remained unchanged, further reducing potential confounding. Lastly, the proposed multivariable model does not equal a risk scoring tool and should be validated in future larger studies.

CONCLUSIONS

Vascular exposure in the groin carries a non-negligible risk of SSI. In this study, we provided important insights that simple and easily viable precautions (such as the universal use of surgical masks both for patients and healthcare professionals during wound care, the widespread diffusion of hand sanitizers, and the reduction of the number of visitors in the surgical wards) could be promising and safe tools for SSI risk reduction.

FIGURE/TABLE LEGENDS

- **Figure 1.** Diagram showing main infrastructural changes to clinical care in the surgical ward between pre-COVID-19 era vs. COVID-19 era
- **Figure 2.** Clinical outcomes at 30 days. A) Amputation & Mortality; B) SSI.
- **Table I.** Baseline characteristics of the study cohort.
- **Table II.** Multivariate logistic regression for independent predictors of SSI. A) Any SSI; B) Deep SSI; C) Superficial SSI.

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Table I. Baseline characteristics of the study cohort.

Variable	Overall cohort *n=194*	Pre-SARS-CoV2 era (2018-2019) *n=143*	SARS-Cov2 era (2020) *n=51*	*P* value	Pre-SARS-CoV2 era (2018) *n=60*	Pre- SARS-CoV2 era (2019) *n=83*	P value
Demographics & Risk factors							
Age (years)	75,3 ± 9,2	75,5±9,3	74,7±8,9	.57	74,52±10,4	76,19±8,4	.29
Age >80 y	72 (37,1)	53 (37,1)	19 (37,3)	.98	20 (33,3)	33 (39,8)	.43
Males	140 (72,2)	101 (70,6)	39 (76,5)	.42	38 (63,3)	63 (75,9)	.10
Smoking	125 (66,1)	94 (67,1)	31 (63,3)	.62	38(65,5)	56(68,3)	.73
Body Mass Index	25,4 ± 3,6	25,3 ± 3,9	25,3 ±2,6	.96	24,8 ± 3,8	25,7 ± 3,8	.23
Obesity	17 (10,4)	15 (11,7)	2 (5,7)	.30	6 (10,9)	9 (12,3)	.81
Dyslipidemia	100 (51,5)	75 (52,4)	25 (49)	.67	27 (45)	48 (57,8)	.13
Diabetes	75 (38,7)	54 (37,8)	21 (41,2)	.67	17 (28,3)	37 (44,6)	.06
SVS scre	3,3 ± 2,4	3,31 ± 2,2	3,31 ± 2,7	.99	2,88 ± 2,2	3,63 ± 2,2	.06
ASA score	140 (72,5)	106 (74,6)	34 (66,7)	.16	47 (78,3)	59 (72)	.39
Clopidogrel	49 (25,4)	39 (27,5)	10 (19,6)	.14	19 (31,6)	20 (24.0)	.11
Direct Oral Anticoagulants	12 (6,1)	9 (6,3)	3 (5,8)	.48	2 (3,3)	7 (8,5)	.22
Statins	94 (48,7)	71 (50)	23 (45,1)	.55	31 (51,7)	40 (48,8)	.73
Warfarin	22 (11,4)	15 (10,6)	7 (13,7)	.54	5 (8,3)	10 (12,2)	.46
Albuminemia (g/dL)	3,8 ± 0,6	3,7 ± 0,6	3,7 ± 0,5	.82	3,5 ± 0,6	3,9 ± 0,5	.09
Hypoalbuminemia	51 (33,1)	38 (33,6)	13 (31,7)	.82	13 (21.6)	25 (30.1)	.07
Hemoglobin (g/dL)	12,1 ± 2,1	12,2 ± 2	11,5 ± 2,4	**.04**	11.9 ± 1,9	12,6 ± 1,9	.10
Anemia	107 (55,2)	73 (51)	34 (66,7)	**.04**	29 (48.3)	44 (53.0)	.22
Leucocytosis	40 (20,6)	27	13	.31	11 (18,3)	16 (19.2)	.85

		(18,9)	(25,5)				
Procedural details							
Rutherford category 5-6	57 (29,5)	38 (26,8)	19 (37,3)	.15	18(30,5)	20(24,1)	.39
Urgent operation	166 (86)	127 (89,4)	39 (76,5)	**.02**	55(91.2)	72(86.7)	.12
Graft needed Patch Bypass	158 (81,9) 75 (47,5) 83 (52,5)	117 (82,4) 60 (51,3) 57 (48,7)	41 (80,4) 15 (36,6) 26 (63,4)	.75 .11	46(78,0) 23(50) 23(50,0)	71(60,7) 37 (52.1) 34(47,9)	.24 .82
Patch/Graft Prosthetic Autologous	114 (59,1) 56 (49,1) 58 (50,9)	79 (55,6) 44 (55,7) 35 (44,3)	35 (68,6) 12 (34,3) 23 (65,7)	.11 **.03**	36(61,0) 18(50,0) 18(50,0)	43(51,8) 17(39,5) 26(60,5)	.27 .35
Proximal Endovascular Associated	85 (43,8)	64 (44,8)	21 (41,2)	.66	26 (43.3)	38 (45,8)	.86
Distal Endovascular Associated	38 (19,6)	21 (14,7)	17 (33,3)	**.004**	9 (15)	12 (14,5)	.93
Operative time (minutes)	175 ± 98	160 ± 76	218 ± 135	**<.001**	160 ± 77	160 ± 75	.95
Clip skin closure	76 (39,2)	52 (36,4)	24 (47,1)	.18	24 (40)	28 (33,7)	.44
Post-op antibiotic >24 hours	61 (31,4)	44 (30,8)	17 (33,3)	.73	19 (31.6)	25 (30.1)	.84
Lenght of stay in hospital (days)	9 ± 9	9±9	7±7	.15	9±8	7±7	.21
Home discharge	69 (35,6)	47 (32,9)	22 (43,1)	.18	21 (35)	26 (31,3)	.64
Post-operative transfusions	33 (17)	25 (17,5)	8 (15,7)	.77	12 (20)	13 (15,7)	.53
Hospitalization in intensive care	44 (22,7)	28 (19,6)	16 (31,4)	.08	9 (15)	19 (22,9)	.24

Table IIA. Multivariate logistic regression for independent predictors of any SSI.

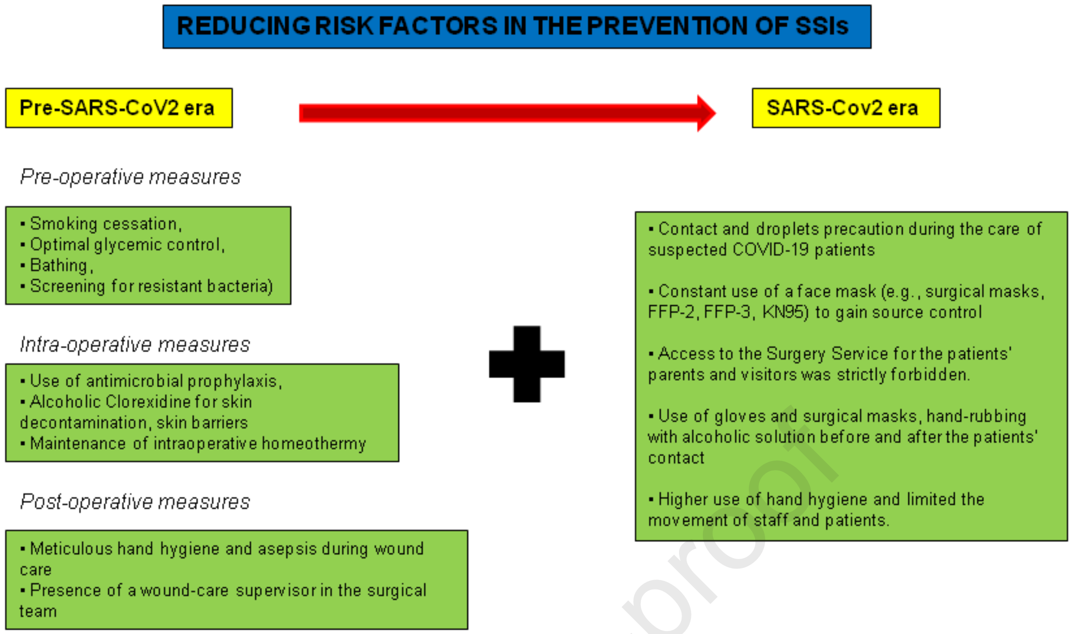
Variables	**OR**	**CI 95%**	**P value**
Pre operative anemia	1.40	0.69-2.85	.34
Distal endovascular associated	0.46	0.15-1.38	.16
Operative time	1.01	0.99-1.01	.22
Timing (urgency)	1.41	0.82-2.42	.24
COVID era	0.31	0.09-0.76	**<.001**

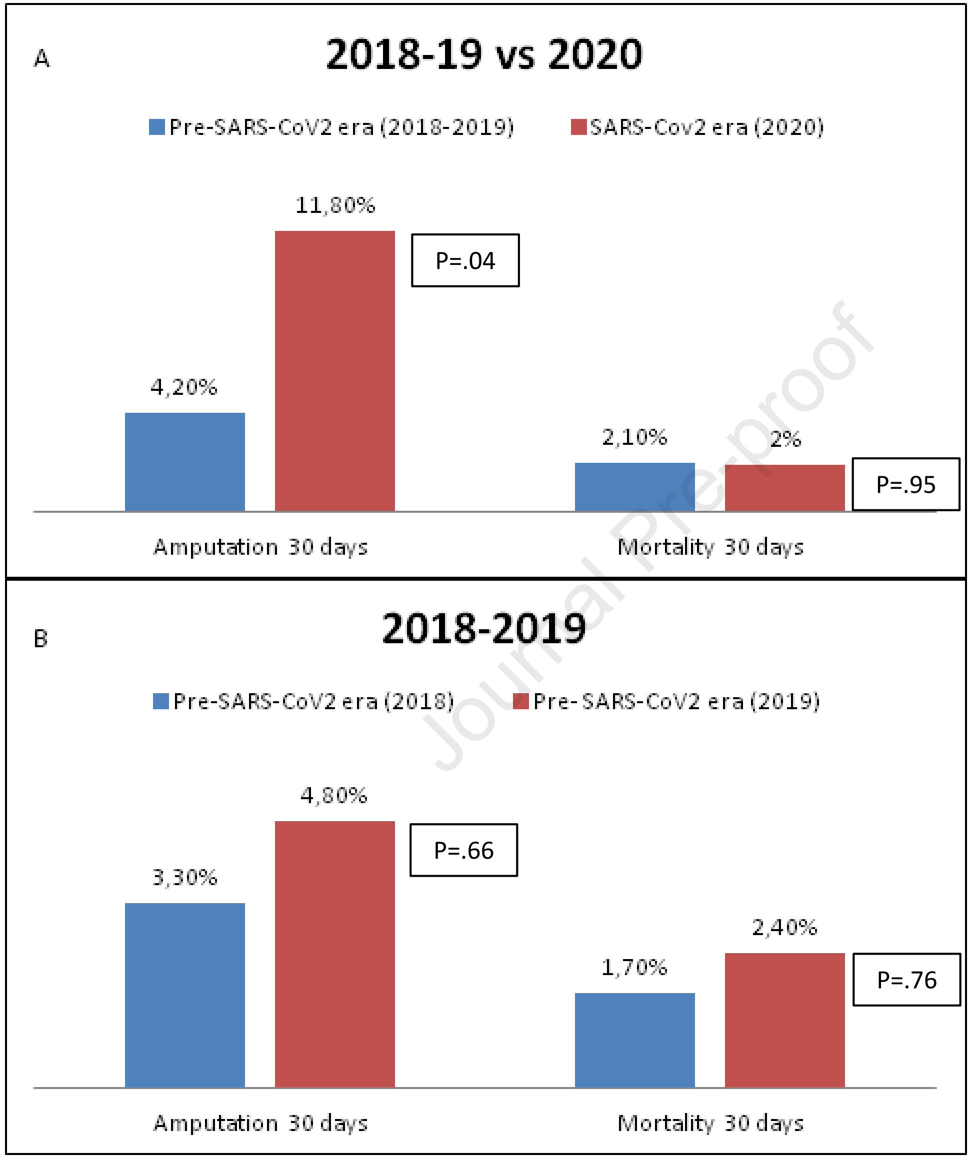
Table IIB. Multivariate logistic regression for independent predictors of deep SSI.

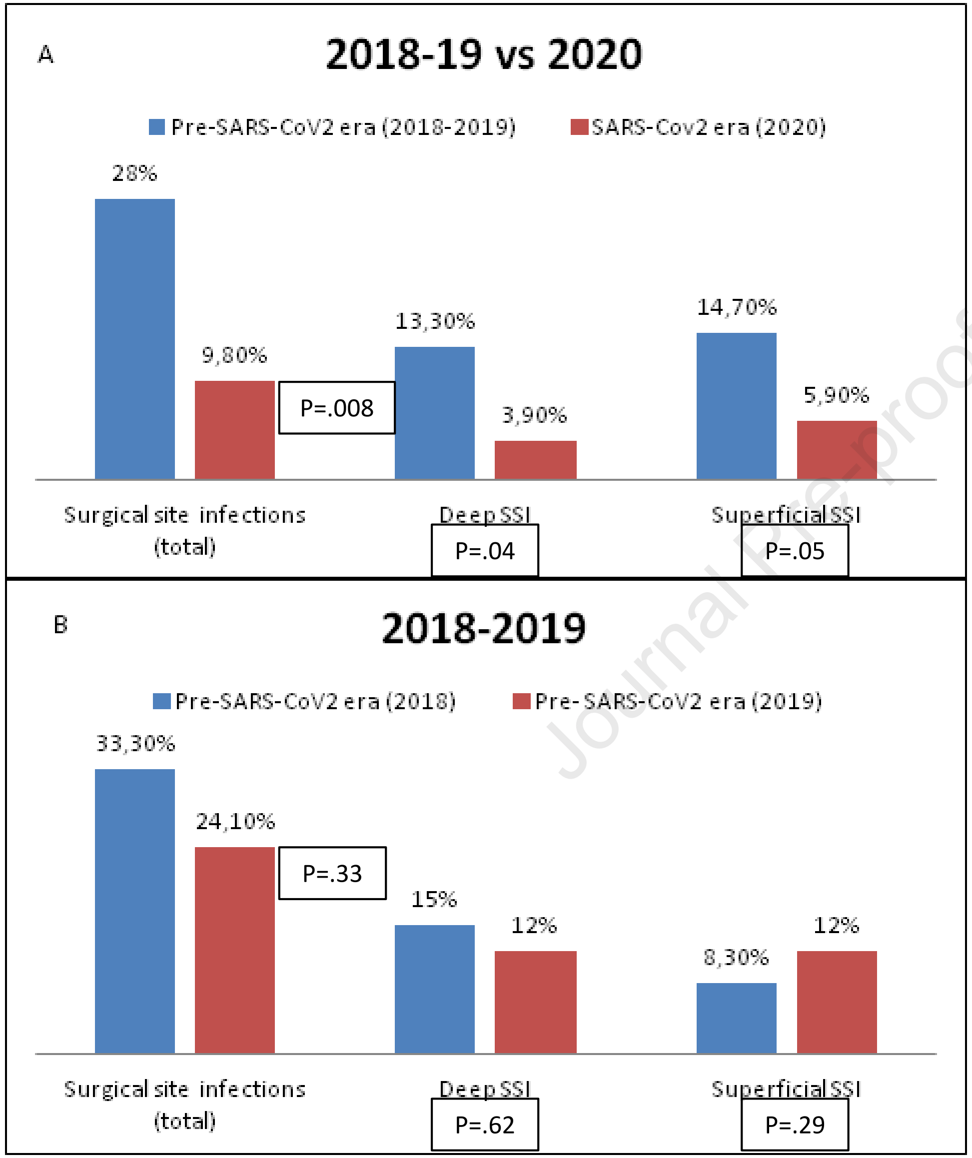
Variables	**OR**	**CI 95%**	**P value**
Pre operative anemia	1.81	0.67-4.87	.23
Distal endovascular associated	0.13	0.01-1.14	.66
Operative time	1.11	1.21-1.52	**.02**
Timing (urgency)	1.5	0.79-3.41	.41
COVID era	0.21	0.03-0.98	**<.001**

Table IIC. Multivariate logistic regression for independent predictors of superficial SSI.

Variables	**OR**	**CI 95%**	**P value**
Pre operative anemia	1.14	0.43-2.52	.91
Distal endovascular associated	1.21	0.33-3.8	.83
Operative time	0.96	0.99-1.01	.47
Timing (urgency)	1.54	0.45-2.87	.48
COVID era	0.49	0.11-1.45	.16


REDUCING RISK FACTORS IN THE PREVENTION OF SSIs
Pre-SARS-CoV2 era
SARS-Cov2 era
Pre-operative measures
• Smoking cessation,
• Optimal glycemic control,
• Bathing,
• Screening for resistant bacteria)
Intra-operative measures
• Use of antimicrobial prophylaxis,
• Alcoholic Clorexidine for skin decontamination, skin barriers
• Maintenance of intraoperative homeothermy
Post-operative measures
• Meticulous hand hygiene and asepsis during wound care
• Presence of a wound-care supervisor in the surgical team
• Contact and droplets precaution during the care of suspected COVID-19 patients
• Constant use of a face mask (e.g., surgical masks, FFP-2, FFP-3, KN95) to gain source control
• Access to the Surgery Service for the patients' parents and visitors was strictly forbidden.
• Use of gloves and surgical masks, hand-rubbing with alcoholic solution before and after the patients' contact
• Higher use of hand hygiene and limited the movement of staff and patients.


A
2018-19 vs 2020
Pre-SARS-CoV2 era (2018-2019)
SARS-Cov2 era (2020)
11,80%
P=.04
4,20%
2,10%
2%
P=.95
Amputation 30 days
Mortality 30 days
B
2018-2019
Pre-SARS-CoV2 era (2018)
Pre- SARS-CoV2 era (2019)
4,80%
P=.66
3,30%
2,40%
1,70%
P=.76
Amputation 30 days
Mortality 30 days


A
2018-19 vs 2020
Pre-SARS-CoV2 era (2018-2019)
SARS-Cov2 era (2020)
28%
9,80%
P=.008
13,30%
3,90%
14,70%
5,90%
Surgical site infections (total)
Deep SSI
P=.04
Superficial SSI
P=.05
B
2018-2019
Pre-SARS-CoV2 era (2018)
Pre- SARS-CoV2 era (2019)
33,30%
24,10%
P=.33
15%
12%
8,30%
12%
Surgical site infections (total)
Deep SSI
P=.62
Superficial SSI
P=.29